



April 14, 2006

Ms. Valerie Frances, Executive Director and  
Members of the National Organic Standards Board

National Organic Program  
1400 Independence Avenue, SW.  
Room 4008-So., Ag Stop 0268  
Washington, DC 20250-0200

**Re: Evaluation of the NOSB Recommendation on the Definition of  
Synthetic Recommended Framework to Further Clarify the Definition  
of Synthetic**

Dear Ms. Frances and Members of the NOSB,

Thank you to the National Organic Program (NOP) for the thorough, detailed and well organized documents presented for discussion by the NOSB Joint Materials and Handling Committee at the upcoming April 18-20 2006 meeting. We appreciate the request made by NOP for the Board to clarify its recommendation of August 17, 2005 for guidance of the review of synthetic and non-synthetic substances. Please accept our compliments to the NOP for the evaluation and recommendation to assist the Board in responding to that request.

**Florida Crystals Food Corp.** as a major producer of organic sugar, sugar products and organic rice sweeteners has been observing and participating in the deliberation of the definition of Synthetics and thanks the National Organic Standards Board (NOSB) for accepting our comments and continued input.

Please contact us if you would like any additional information from us that might help you in this process and thank you again for your collaborative effort and awareness of the complexity of this effort.

Sincerely,

**Michael DeLuca**  
**Vice President**  
**Development**  
**Natural Foods Group**  
**Florida Crystals Food Corp.**

**Stephen Clarke, Ph.D.**  
**Director, Industrial Research and**  
**Okeelanta Corporation**  
**Florida Crystals Food Corp.**

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**Comment to the National Organic Standards Board  
Joint Materials and Handling Committee  
April 20, 2006**

**RE: EVALUATION OF THE NOSB RECOMMENDATION ON THE DEFINITION OF SYNTHETIC**

Florida Crystals Food Corp. agrees with the intention of the evaluation to suggest ways of improving clarity and avoiding potential difficulties of the practical application of the previous NOSB recommendation.

Our comments to this document address two specific areas:

- The need of the NOSB to fully explain the purpose of the recommendation and include a "clear explanation of the intent (in) each definition and policy position"
- The suggestion that the definition of "substance" may be qualified by the possession of a distinct identity such as an individual Chemical Abstract Service number.

**General Comments:**

Florida Crystals Food Corp. presents our comments from the perspective of a certified organic handler and reflect our interpretation of the definition of synthetic and non-synthetic as they pertain to organic handling standards and certification.

Throughout the evaluation, we notice the repeated reference to the need to state or clarify the purpose, objective and intentions of the NOSB recommendation.

We believe that this is the overarching prerequisite and most important aspect that has, up until now, not surfaced as an essential part of the ongoing deliberation.

We believe that it is absolutely necessary that the NOSB and the NOP find common ground in a logical and completely understood explanation and rationale for the underlying principle inherent in defining synthetic and non-synthetic.

We are aware of the original intention in organic standards to prohibit the use of toxic, persistent petroleum based chemicals in agricultural production and the addition of food additives, preservatives and artificial ingredients that are derived from petroleum based chemicals in food processing. We also understand the expectation of consumers that nothing with an organic label would contain any of those substances. Most of these concerns are addressed by the criteria to place a substance on the National List as stated in the Organic Foods Production Act, which admittedly are open to interpretation that should be more specifically detailed. This effort has led us to this point.

We urge the NOSB to look, as well, beyond the science and syntax and balance the original intention of organic production and handling with the necessary caution needed to avoid any jeopardy of organic integrity in the definition of a synthetic or non-synthetic as these terms are used to identify substances for placement on the National List.

**We strongly suggest that the NOSB consider any substances that are produced entirely from natural sources, without any prohibited methods, without the inclusion of any petroleum based compounds, without any diversion from the OFPA criteria, whether by extraction, formulation or manufacturing, or by processes that are naturally biologically occurring or already permitted as processes to produce final products as food, not be considered synthetic for the purposes of this definition.**

In the following comments, we will refer to instances where attention to this balance seems to be appropriate and necessary.

#### **Specific Comments on Numbered Items in the NOSB Recommendation:**

##### **1. Comments on "Extraction"**

We agree that a separate definition of "natural source" is a logical addition and that it be expanded to include other specific categories of substances of biological origin.

We agree that the definition of "extraction" may need to be separated from the three ideas relevant to the purpose of the NOSB recommendation. We agree with the definition as stated, "the removal of a substance from a natural source by any chemical...or physical manner with any substance."

We notice that this section makes reference again to the need for the NOSB intent, here as it applies to "insignificant levels" of substances used in the extraction process.

##### **2. Comments on "Formulation or Manufacturing"**

We agree that while formulation is not specifically defined in the NOSB recommendation, we support the suggested definition of "formulation" as the manufacture of an agricultural or handling input

that is derived from a substance *extracted* from a natural source....." and that this definition be expanded to include processes other than *extraction* alone.

We disagree with the evaluation's suggestion that the chemical changes during processing should be discussed separately from chemical changes during "formulation".

We agree that use of the specific term "chemical reaction" as a result of formulation may be problematic.

### **3. Comments on the Definition of "Processing"**

We agree that this definition should be cited in the context of the relevant discussion rather than as a stand-alone item and we add that the definition of processing be considered in its fullest context, as methods allowed for the production of food.

### **4. The Definition of "Chemical Reaction"**

We emphatically agree that the existing NOSB recommendation to define as synthetic any substance that undergoes chemical reaction during extraction or formulation is excessively limiting, not only for the reasons stated, but for the reason that some substances that are benign by all other criteria would be categorized as synthetic simply by the occurrence of chemical change, which in the production of food, is quite common. It should be recognized similarly in the production of inputs allowed for the processing of food when all other reasonable criteria are met.

**We agree with the option to address these limitations "to permit certain types or ranges of reaction that would not go against the underlying objective of the NOSB recommendation." This calls for the question of what that underlying objective is.**

We *disagree* strongly with the suggestion that the apparent intention could be to prevent a non-synthetic naturally occurring substance of biological origin that is transformed into a new substance by any means other than naturally occurring biological processes, to be called a non-synthetic without consideration of all criteria on a case by case basis and with the consideration of the over arching intent of the recommendation, still needing clear expression.

**We agree with the evaluation that "a direct statement of the objectives and intentions of the recommendation would be helpful to resolve any unforeseen uncertainties that may arise in their application to specific substances."**

### **5. "Substance"**

We disagree with the suggestion in the evaluation that a substance be defined as a compound or element that has a distinct identity, such as a separate CAS number.

In support of our disagreement we point out that a number of substances currently on the National List Section 205.605(a) Non-Synthetics are listed as single substances but in practice are available in three forms, each with a separate CAS number. Please note the following examples:

**Calcium Sulfate** - Available in three forms, each with different CAS number:

- Anhydrous calcium sulfate 7778-18-9
- Calcium sulfate hemihydrate 10034-76-1
- Calcium sulfate dihydrate 10101-41-4

**Magnesium Sulfate** - Available in three forms, each with different CAS number:

- Anhydrous magnesium sulfate 7487-88-9
- Dried magnesium sulfate 22189-08-8
- Magnesium sulfate heptahydrate 10034-99-8

**Sodium Carbonate** - Available in three forms, each with different CAS number:

- Anhydrous sodium carbonate 497-19-8
- Sodium carbonate monohydrate 5968-11-6
- Sodium carbonate decahydrate 6132-02-1

If a single CAS number were to be used it would be necessary to specify which of the forms (hydrates) occurs naturally and in some cases more than one form can occur naturally in different mined locations, even mixed at the same location. In most cases the mined minerals are not of sufficient purity or quality to be suitable for use in food production and their use requires purification by heating, crystallization, or other processes.

**This presents an obvious ambiguity in which the intended substance on the National List as a non-synthetic, in another form, would be a synthetic.**

**RE: RECOMMENDED FRAMEWORK TO FURTHER CLARIFY THE DEFINITION OF SYNTHETIC**

Florida Crystals Food Corp. agrees with the premise of the recommendation to create a framework for determining whether a

substance is Synthetic or Non-synthetic as it pertains to placement of the substance on the National List.

Our comments to this document address one specific aspect:

- The relationship between the definitions of Extraction, Formulation, Manufacturing and Processing

## **Section 2.2      Proposed New Definitions**

We agree with the inclusion of the new definitions "natural source" and "formulation (manufacturing)" and suggest the expansion of the definition of natural source as stated in the previous section.

We reiterate that formulation (manufacturing) not be limited to inputs that have been *extracted*, but be expanded to include other processes of manufacturing.

We add that the process of formulation as a synonym for manufacturing cannot be simply related to the use of the term in the OFPA definition of "synthetic" since OFPA also references "manufacturing" in the definition of "processing":

**"Processing - the term "processing" means cooking, baking, heating, drying,.....or otherwise manufacturing....."**

This leads to the potential interpretation that "manufacturing" and thus in this case, "formulation" as well, would include the methods defined as "processing" in OFPA.

**As a further explanation, if a processing method is allowed to manufacture ingredients into food, it reasonably cannot be disallowed for the manufacturing of the naturally occurring sources of those ingredients, or for that matter, the naturally occurring sources of processing aids, that unlike ingredients do not remain in the final product.**

**We suggest therefore, that the proposed new definition of formulation (manufacturing) include the methods allowed for processing as defined in OFPA.**

Rather than restate the observation of Section 205.605(a) regarding the proposed new definitions for Substance and Chemical Change, please see our previous comment to the evaluation.

## **Section 3.3      Formulation (Manufacturing)**

We suggest that this section reflect the observations already stated in this comment and that an apparent confusion be corrected.

It is not clear how a formulated substance that contains a synthetic substance would qualify as a non-synthetic substance. A non-synthetic formulated substance cannot reasonably contain *only* non-synthetic substances **and** synthetic substances, simply because the synthetic

substance is already on the National List. This would produce a non-synthetic substance from a synthetic substance. This does not appear logical.

#### **Section 3.4            Substance**

Please reference our previous comments to the evaluation document regarding the definition of substance.

#### **Section 3.6            Chemical Change**

Based on the explanations in sections noted above, in the context of producing (extracting, formulating, manufacturing, processing) inputs for use in food production, it is a natural extension of these definitions to notice that the manufacturing of final processed food products produces products in which chemical change has occurred.

**It would seem very ambiguous that in the product that is allowed for human consumption as food, chemical change is not only permitted, but assumed and never is such a food called a synthetic. And this is what we eat!**

**How then, if only naturally occurring materials of biological origin, (plants, animals, minerals, even fungi and microorganisms) are the only materials used, can the processes allowed produce a substance in which chemical change has occurred now be called a synthetic, simply because chemical change occurred and resulted in a distinctly new substance.**

This is what happens, and has always happened throughout time, in the production of the food we eat. It follows that the same criteria should be allowed for those naturally occurring substances that are used to produce that food.

#### **Summary**

We hope these comments will add substantively to the discussion and will highlight the importance of the NOSB's consideration of all the implications of the definitions of synthetic and non-synthetic in this context.

Thank you very much to the NOP and the NOSB for the opportunity to express our opinions and share our perspective with you.

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